Health Care Update

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Agenda

- Legislation in the pipeline
- How the election will impact health policy in the near term
- Compliance issues: the No Surprises Act, MHPAEA and Consolidated Appropriations Act
- Questions you should be asking.

Legislation in the Pipeline

Taxation of Employee Benefits

- March 20, 2024, the Republican Study Committee released its Fiscal Year 2025 Budget proposal
- The proposal would cap the exclusion from income for employer-sponsored health insurance and promote the use of Individual Coverage Health Reimbursement Arrangements (ICHRA)
  and individual insurance
  under the ACA Exchanges

Employer Community Responds

- Employee benefits advocacy groups responding to RSC, often in conjunction with ERISA at 50 events
- Concern is potential legislative activity in reconciliation

Courtney Opposes Taxation of Benefits

- Representative Joe Courtney (D-Conn) wrote op-ed in Roll Call April 10, 2024
  - *Taxing health insurance: The Republican zombie that refuses to die*

House Committee on Education and the Workforce RFI on ERISA

- ERISA's 50th Anniversary: Reforms to Increase Affordability and Quality in Employer-Sponsored Health Coverage
- RFI requests information on broad scope of issues, including preemption, fiduciary requirements, reporting requirements, prohibited transactions, data sharing, cybersecurity, broker compensation, the ERISA Advisory Council, and COBRA
- Multiple groups provided comments, including National Coordinating Committee for Multiemployer Plans (NCCMP), American Benefits Council, the ERISA Industry Committee and more

Committee Holds ERISA Hearing

- April 16, 2024 Subcommittee on Health, Employment, Labor, and Pensions held hearing
  - *ERISA's 50th Anniversary: The Path to Higher Quality, Lower Cost Health Care*
- Witnesses emphasized the importance of ERISA preemption, which ensures that multi-state plan sponsors can provide uniform and consistent benefits to plan participants

PBMs Under the Microscope in Congress

- Various Senate and House bills introduced concerning pharmacy benefit manager ("PBM") reform
- Key focus areas include:
  - Requiring transparency in reporting, including rebates
  - Prohibiting spread pricing, in which PBMs charge health plans more than they reimburse to pharmacies
  - Requiring PBMs to pass on all rebates and fees collected from manufacturers to health plans
  - Prohibition on claw backs, which are frequently obtained through high copayments.

Senate *Pharmacy Benefit Manager Reform Act*

Reported by Senator Sanders to the Committee on Health, Education, Labor, and Pensions on June 22, 2023 (S 1339)

- PBMs must report annually to the plan sponsor certain information about the PBM's services, including amount of copayment assistance funded by drug manufacturers, list of covered drugs billed under the plan during the reporting period, and total net spending by the health plan on prescription drugs
- PBMs also must provide plan sponsors with a supplementary report every six months with specified information about drugs that dispensed under the plan by pharmacies wholly or partially owned by the PBM

House *Lower Costs More Transparency Act*

Energy and Commerce, Ways and Means and Education and the Workforce Committees combined legislation into the Lower Costs More Transparency Act (HR 5378)

Passed House December 11, 2023

- General hospital transparency provisions that expand current laws
- PBM transparency and employer reporting requirements
- Bans spread pricing in Medicaid
- Community health center pricing

Senate *Health Care Prices Revealed and Information to Consumers Explained Transparency Act (S 3548)*

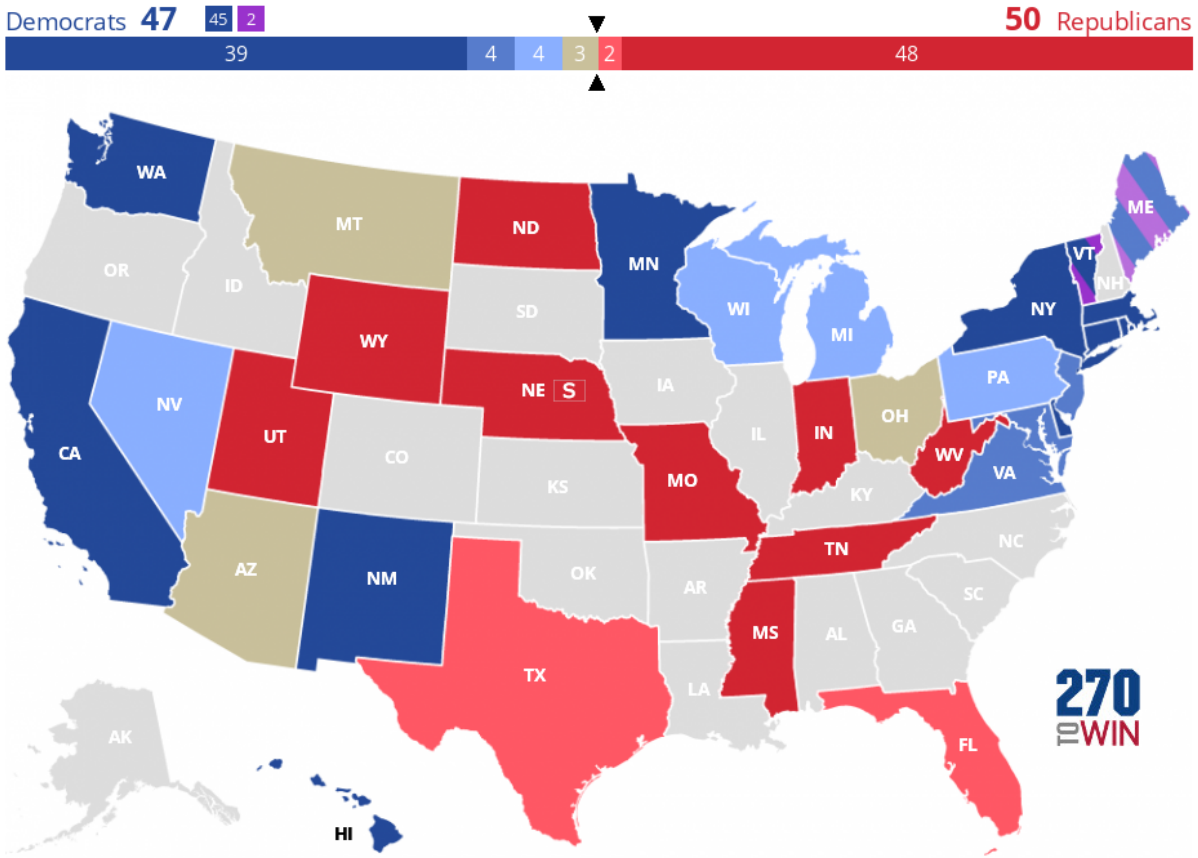
- Introduced by Sen. Mike Braun (R-IN)
- Would expand current transparency disclosure requirements
- Would amend ERISA Section 408(b)(2) to require contract terms between the plan and service providers, and attestation of compliance

How the Election May Affect Health Care Policy in the Near Term

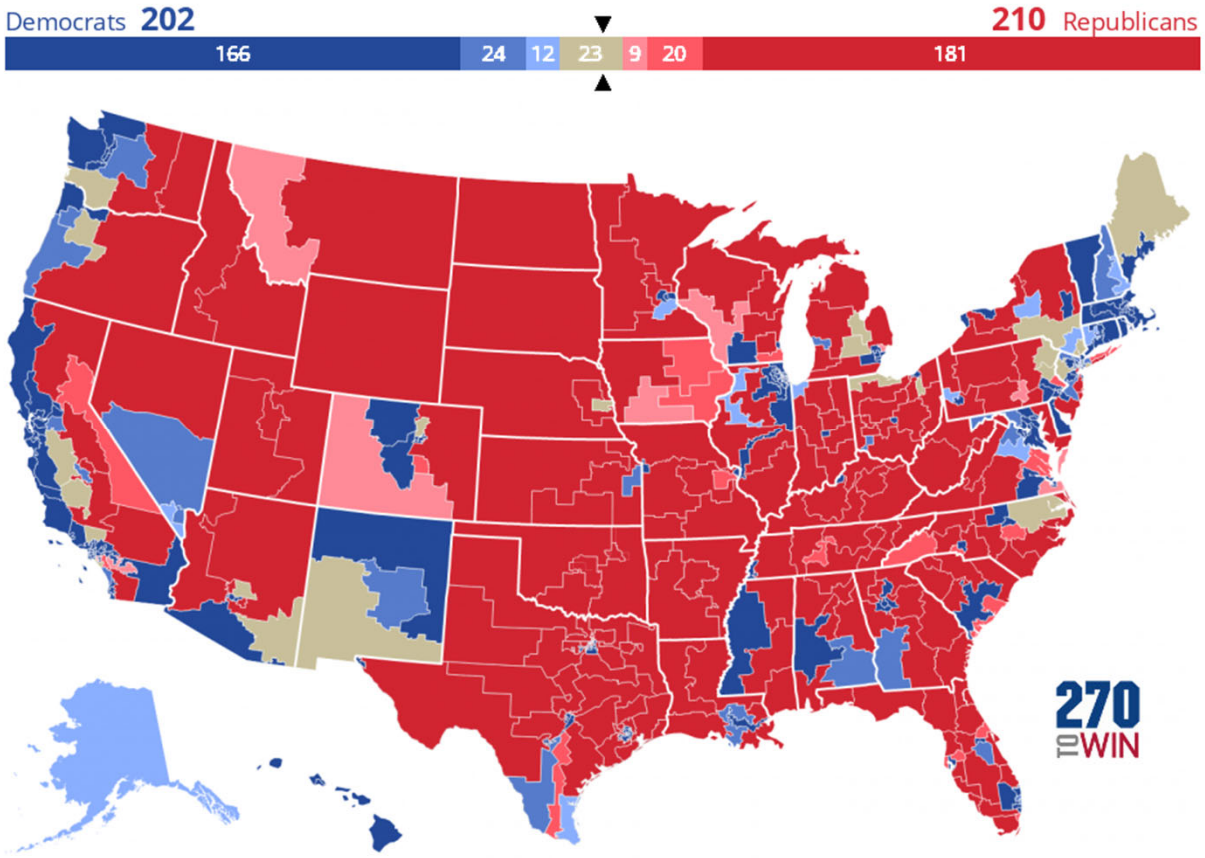
Latest Developments

- Mike Johnson (R-LA) assumed the House Speaker position in October 2023
- April 24, 2024, President Biden signed an aid package worth $95 billion, including $61 billion in aid to Ukraine, $26 billion to Israel, and $8 billion for the Indo-Pacific
  - The package also gives Chinese parent company ByteDance nine months to sell TikTok or else it will be banned from U.S. app stores

2024 Senate Election Map



2024 House Election Map



2024 Lame Duck Health Care Package

- Must-have tax extenders: Medicare telehealth flexibilities, Medicare physician payment bump, community health center funding
- Potential legislation
  - PBM disclosure requirements
  - Transparency in coverage disclosure requirements
  - $35 cost-sharing cap for insulins in employment-based coverage

What Rolls Over to the Next Congress?

- PBM legislation banning spread pricing or requiring 100% rebate pass through (for employer sponsored coverage and Part D)
- Longer term community health center funding
- Attempts to modify ERISA preemption

The Regulatory Push

Regulatory Activity

- The Administration is publishing final rules at a fast pace to avoid new regulations falling victim to the Congressional Review Act
- The Act gives Congress 60 legislative days to disapprove of a final regulation, which can then be reconsidered in the next Congress

Congressional Review Act period could begin as early as mid-May

Regulations Recently Published

- Final rule on definition of an investment advisor fiduciary (April 23, 2024)
- Final rule on overtime pay regulations under the Fair Labor Standards Act (FLSA) (April 23, 2024)
- HHS may issue rulemaking on the ACA and cost sharing with respect to copay accumulator programs

New April 2024 Final Rules Affecting Group Health Plans

- HIPAA and Reproductive Rights
- ACA Section 1557 Nondiscrimination
- Association Health Plans

HIPAA Reproductive Care Regulation

- HHS Office for Civil Rights (OCR) published HIPAA Privacy Rule to Support Reproductive Health Care Privacy (April 22, 2024)
- Prohibits the disclosure of protected health information (PHI) related to lawful reproductive health care in certain circumstances
- Compliance date December 23, 2024; New Notices of Privacy Practices due February 16, 2026

HIPAA Reproductive Care Regulation

- Prohibits the use or disclosure of PHI when it is sought to investigate or impose liability on individuals, health care providers, or others who seek, obtain, provide, or facilitate lawful reproductive health care, or to identify persons for such activities
- Requires a regulated health care provider, health plan, clearinghouse, or their business associates, to obtain a signed attestation that certain requests for PHI potentially related to reproductive health care are not for these prohibited purposes
- Requires regulated health care providers, health plans, and clearinghouses to modify their Notice of Privacy Practices to support reproductive health care privacy

ACA Section 1557 (Nondiscrimination in Health Benefits)

- April 26, 2024, HHS released new final 1557 regulation (to be published May 6, 2024)
- Entities that receive federal financial assistance from HHS cannot discriminate on the basis of race, color, national origin, sex, age or disability with regard to health programs

Association Health Plans

- DOL released a final rule, to be published April 30, 2024, that rescinds the 2018 Trump-era regulation that expanded the definition of "employer" to allow businesses to more easily pool together to buy health insurance
- The 2018 rule had been overturned by a U.S. District Court in 2019
- The new final rule will be effective 60 days after publication

Eating Disorders Are Mental Health Conditions

- EBSA Assistant Secretary Lisa Gomez wrote that people seeking treatment for eating disorders, such as therapy, medications, nutritional counseling, or residential treatment programs, should not face barriers or roadblocks that do not exist for medical treatments (Feb. 29, 2024)
  - "[I]f a health plan provides coverage for nutritional counseling for someone with diabetes, it cannot have a blanket exclusion for coverage of nutritional counseling for those with eating disorders."

Taxation of Work-Life Referral Services

- FS 2024-13, April 2024, states that work-life referral services (also called caregiver or caretaker navigation services) that provide informational and referral consulting to help participants identify, contact, and negotiate with life management resources are a de minimis fringe benefit, are excluded from gross income and not subject to U.S. employment taxes

Food Is Not a Reimbursable Medical Expense

- The IRS issued an alert March 6, 2024, reminding consumers and health plan sponsors that expenses that are merely beneficial to general health, including for nutrition and wellness, are not medical expenses
- Recent marketing by weight loss and home-delivery meal services suggested this food was reimbursable with a doctor's note—That is not the case

Importation of Prescription Drugs

- October 2020 FDA published final rules creating two pathways toward importation:
- Pathway 1—States and Indian tribes may apply for a program under Section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allows importation of certain prescription drugs from Canada to if they:
  - Significantly reduce the cost of these drugs to the American consumer,
  - Do not impose additional risk to public health and safety
- Pathway 2—Manufacturers could import versions of their drugs that they sell in other countries

Florida's SIP Authorized

- On January 5, 2024, Florida's SIP was authorized for two years from the date the FDA is notified of the first shipment of drugs to be imported. Florida must:
  - Submit additional drug-specific information for the FDA's review and approval
  - Ensure that the drugs Florida seeks to import have been tested for, among other things, authenticity and compliance with the FDA-approved drugs' specifications and standards
  - Relabel the drugs to be consistent with the FDA-approved labeling

Details Still Emerging on Florida's Program

- Florida will begin by providing prescription drugs in a small number of drug classes which will include maintenance medications to help individuals who have chronic health conditions such as HIV/AIDS, mental illness, prostate cancer, and urea cycle disorder
- Drugs will only be for institutionalized individuals (Agency for Persons with Disabilities (APD), Department of Children and Families (DCF), Department of Corrections (FDC), and Department of Health (DOH))
- Later, the program will expand to Medicaid eligibles
- Program not available for state government employees at this time

Regulations in the Pipeline

- Mental Health Parity and Addiction Equity Act
- Advanced Explanation of Benefits
  - CMS issued update April 23, 2024 on AEOB and Good Faith Estimate (GFE) but indicated development of technical standards will take time

Compliance Issues

Preventive Services Update

- The ACA's preventive services mandate requires non-grandfathered group health plans and insurers to cover certain preventive services with no cost sharing on an in-network basis

No Cost Sharing Preventive Services

- The following preventive services are covered:
  - The USPSTF recommends "A" or "B" rating [1] for specific evidence-based items and services for all patient demographics
  - The Health Resources and Services Administration (HRSA[2]) issues guidance regarding preventive care and screening for infants, children, adolescents and women
  - The Advisory Committee on Immunization Practices (ACIP[3]) recommends certain immunizations

1 https://uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations
2 https://www.hrsa.gov/
3 https://www.cdc.gov/vaccines/acip/index.html

Litigation Update: Braidwood Management Inc. v. Becerra

- On March 30, 2023, Judge Reed O'Connor of the U.S. District Court for the Northern District of Texas ruled that part of that mandate violates the Constitution and vacated all agency action taken to implement or enforce the USPSTF "A" or "B" preventive care recommendations on or after March 23, 2010

The Case Continues . . .

- June 13, 2023: The Fifth Circuit Court of Appeals stayed the lower court's order
  - Provider groups agreed not to oppose agencies' motion to stay the lower court's decision
  - Agencies agreed not to seek penalties or enforcement for periods before the case is resolved
- Stay means that non-grandfathered health plans must continue to provide the USPSTF "A" and "B" preventive services with no cost-sharing while the *Braidwood* decision is being appealed

President's Executive Order on Contraception and Family Planning Services

- On June 23, 2023, the President issued Executive Order 14101, "Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services" (E.O. 14101)
- The Order directs the Secretaries to consider issuing guidance to further improve Americans' ability to access contraception, without out-of-pocket expenses, under the ACA and to consider additional actions to promote increased access to over-the-counter contraception, including emergency contraception

Preventive Service FAQs Part 54 (2022)

- FAQ 54 explains that plans and issuers, among other thing, must cover without cost sharing
  - At least one form of contraception in each of the categories listed in the HRSA-supported Guidelines; and
  - Cover without cost sharing any contraceptive services and FDA-approved, -cleared, or -granted products that an individual and their attending provider have determined to be medically appropriate for the individual, whether or not those services or products are specifically identified in the categories listed in the HRSA-supported Guidelines.

Preventive Service FAQs Part 54

- With respect to those newer contraceptive products and services not included in the categories listed in the HRSA-supported Guidelines, plans and issuers may use reasonable medical management techniques to determine which specific products or services to cover without cost sharing only if at least one of multiple, substantially similar products or services are available and medically appropriate for the individual

Preventive Service FAQs Part 54

- Medical management techniques will generally not be considered reasonable unless the plan
  - Has an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider; and
  - Covers without cost sharing a contraceptive service or FDA -approved, -cleared, or -granted contraceptive product determined to be medically necessary with respect to an individual as determined by the individual's attending provider (including if there is only one service or product that is medically appropriate for the individual, as determined by their attending provider).

Preventive Service FAQs Part 64 (January 2024)

Under the new FAQs plans can continue to comply with existing ACA preventive services guidance OR

With respect to FDA approved drugs and devices, the plan may follow the therapeutic equivalence approach.

The Therapeutic Equivalence Approach

- Applies to FDA-approved contraceptive drugs and devices
- Medical management techniques are considered reasonable if the plan covers all FDA-approved contraceptive drugs and devices in a category without cost sharing, other than those for which there is at least one therapeutic equivalent drug or device that the plan or issuer covers without cost sharing

Example of Therapeutic Equivalent Approach

- FAQ 64 provides an example related to the category of "oral contraceptives (combined pill)"
- Plans may cover several FDA-approved oral contraceptives (combined pill) without cost sharing
- At the same time, the plan may exclude coverage for certain oral contraceptives (combined pill) where there is a therapeutic equivalent that is covered without cost sharing
- This essentially allows the plan to exclude certain brand-name drugs as long as a therapeutically equivalent drug, such as a generic, is covered without cost sharing

Preventive Services and Prescriptions (RFI)

- In a request for information (RFI) published on October 4, 2023, the Departments of Treasury, Labor and HHS asked for comments on whether plans should be required to cover ACA over-the-counter (OTC) preventive services without a prescription
- The RFI looks for comments concerning providing ACA-approved OTC preventive services, including tobacco-cessation pharmacotherapy, folic acid supplements, breastfeeding supplies and certain contraceptives
- Comments were due December 4, 2023, and guidance is still pending

NSA and Transparency in Coverage (TiC) Roundup

- NSA litigation, FAQs, and IDR
- Gag clauses
- Machine readable files, including Rx files
- Internet-based self-service tool

Litigation Update: IDR Process

- On August 24, 2023, in *Texas Medical Association, et al. v. United States Department of Health and Human Services*, the U.S. District Court for the Eastern District of Texas issued a judgment and order vacating certain portions of the Departments' August 2022 final rules (TMA III)
- IDR was paused, and then reopened October 6, 2023, for certain single and batched disputes but continued to pause air ambulance disputes

TMA III Holding

- The district court vacated:
  - Portions of the QPA methodology, including counting rates for all items and services regardless of the number of claims paid; using book of business rates instead of each plan's rates; rules governing calculation of QPA for providers in the same or similar specialty; exclusion of bonus, incentive and risk sharing payments, and exclusion of single case agreements
  - The "clean claim" rule for air ambulance services, which states that the 30-day initial payment period starts when the plan has a clean claim
- The ruling will likely require changes to plan administrators' QPA methodology calculations and cause disruption
- Departments intend to appeal

Departments Respond in FAQ 62

- FAQ 62 issued FAQs in response to the TMA III decision
- Plans must calculate QPAs consistent with the rules that remain in effect after TMA III using a good faith, reasonable interpretation
- The Departments will exercise enforcement discretion for plan QPA calculation in accordance with the July 2021 IFR in effect before TMA III for items and services furnished before May 1, 2024
  - Enforcement discretion also applies to providers who balance bill
- Plans must still disclose the QPA to providers and participants, and should disclose which methodology is used

Final Rule IDR Fees for 2024

- On December 21, 2023, the Departments published a final rule establishing IDR fees effective for disputes initiated on or after the later of the rule effective date or January 22, 2024
- Nonrefundable Administrative Fee: $115 per party per dispute
  - Departments proposed flexibility to modify the fee with notice and comment rulemaking rather than annually to account for program needs
- Entity Fees (refunded to the prevailing party):
  - Single Determinations: $200 to $840
  - Batched Determinations: $268 to $1,173; Batched Determinations with more than 25 line items: $75 to $250 for every additional 25 line items within a batched dispute beginning with the 26th line item

Gag Clause Prohibition Under the NSA

- Effective 12/27/20, health plans and insurers may not enter into contracts that would restrict the plan from:
  - Disclosing provider-specific cost or quality of care information
  - Electronically accessing de-identified claims and encounter information or data consistent with HIPAA, GINA, and ADA
  - Sharing this information/data with a business associate.

Gag Clause Attestation—FAQ 57

- Plans must complete attestation that they do not have gag clauses in contracts by December 31, 2023
  - Subsequent attestations due each December 31
- Online forms available
- Determine who will complete the attestation on behalf of the plan
- Legal counsel should review relevant contracts
- Treasury Department stated 10/18/23 that they do not expect to issue additional guidance

Machine Readable Rx File Enforcement Back on Track

- Plans are required to publish on a public website:
  - In-network provider rates (due for plan years beginning on or after 1/1/22)
  - Out-of-network allowed amounts and billed charges (also 1/1/22)
  - Negotiated rates and historical net prices for covered prescription drugs (previously deferred indefinitely)
- FAQ Part 61 (9/27/23) rescinded the enforcement deferral of the Rx machine readable file requirement
- FAQ Part 61 (9/27/23) rescinded the enforcement deferral of the Rx machine readable file requirement

Internet-Based Self-Service Tool—Transparency in Coverage Final Rule

Internet-based self-service tool

- Real time tool a participant can use to search for cost-sharing information that is accurate at the time of request
- Effective for plan years beginning on or after January 1, 2023, with respect to 500 items and services listed in rule
- Effective for plan years beginning on or after January 1, 2024, for all covered items and services

Retiree Plan Design Challenges

- The Inflation Reduction Act was signed August 16, 2022
- The Act was passed using the "budget reconciliation process"
- The Act significantly changes Medicare coverage
  - Medicare will negotiate prices for certain prescription drugs
  - Medicare will receive inflation rebates from manufacturers
  - Part D coverage changes significantly—$2,000 out of pocket maximum, Medicare Payment Plan Program, new manufacturer discount program, and more
  - Additional Medicare coverage for vaccines and insulin

What About Plans That Receive the Retiree Drug Subsidy (RDS)?

- The actuarial value of the Part D benefit is increasing significantly
  - Some group health plans may have retiree drug benefits that don't meet the actuarial standard
- Plan sponsors need to test the value of their drug benefit under the new standard
- If the plan does not meet the standard, they may wish to either increase drug benefits or consider moving from RDS to an Employer Group Waiver Plan (EGWP) with higher federal government subsidies

What About Creditable Coverage Testing?

- Plans must issue Notices of Creditable Coverage each year, telling active employees whether their drug coverage is equal to or better than the Part D benefit
- Because of the improvement in the Part D benefit, some group health plans who previously had creditable coverage may find the coverage is now not creditable
- Medicare-eligible active employees in a drug plan that is not creditable may incur a penalty if they do not enroll in Medicare Part D
- For 2025, current rules on testing will apply, but watch for 2026

Supreme Court Reviewing Administrative Deference

Longstanding Chevron Doctrine

- Under the 1985 U.S. Supreme Court *Chevron v. NRDC* ruling, known as the *Chevron* doctrine, a court gives deference to agency regulatory interpretations:
  - Where the statute is ambiguous, and
  - The agency's interpretation is not "arbitrary and capricious"

Supreme Court Reconsiders *Chevron* Deference

- On January 17, 2023, the United States Supreme Court heard oral arguments in ***Loper Bright Enterprises v. Raimondo*** which challenges the scope of the Chevron doctrine
- The Court will review *Chevron* and could narrow or overrule the existing doctrine
  - The case concerns the 1976 Magnuson-Stevens Act, which requires certain fisheries to allow federal observers onboard to collect data for preventing overfishing; a group of fisheries is challenging the National Marine Fisheries Service's interpretation of this Act, asserting the fisheries are not required to pay the salaries of the observers

Supreme Court Decision on Chevron Pending

- Based on the oral argument and the conservative court majority, it appears unlikely that Chevron will survive, at least in in its current form
- The ruling in this case could have ripple effects across the federal government, where agencies including the Departments of Labor, Health and Human Services and the Treasury frequently issue regulatory guidance that might be more readily challenged in the absence of or with more limited applicability of the Chevron doctrine

Strengthening Parity Mental Health/ Substance Use Disorder

- Enacted December 27, 2020 through CAA 2021
- Requires group health plans to perform and document comparative analyses of the design and application of nonquantitative treatment limitations (NQTLs)
- Plans were required to be prepared to make these comparative analyses available to the Departments of Labor and/or Health and Human Services upon request beginning 45 days after the date of enactment (February 10, 2021)

New Mental Health Guidance Released

- On July 25, 2023, the Departments issued a package of guidance
  - Proposed rules, later formally published in the FR on August 3
  - Technical release seeking information and comments with respect to guidance for proposed data collection and evaluation requirements for nonquantitative treatment limitations related to network composition
  - The 2023 MHPAEA Comparative Analysis Report to Congress
  - Enforcement Fact Sheet regarding fiscal year 2022 enforcement results
  - Press Release announcing guidance

DOL press release frames the guidance **" . . . *an important step in addressing the nation's mental health crisis by proposing rules to better ensure that people seeking coverage for mental health and substance use disorder can access treatment as easily as people seeking coverage for medical treatment."***

Mental Health Parity Proposed Regulations

- The August 3, 2023, proposed rules revise the 2013 final rules as well as including new, additional requirements related to documented NQTL comparative analyses
- Proposed applicability for plan years beginning on and after January 1, 2025

Key Proposed Requirements

- Application of predominant/substantially all testing to NQTLs
- Data collection requirements
- Meaningful benefit requirement
- Prohibition on separate NQTLs targeted at MH/SUD
- New and expanded examples
- Documented comparative analysis content, timing, findings of noncompliance-including named fiduciary certification

Comment Deadline

The Departments solicited comments on all aspects of the proposed rules

In addition, the Departments issued a Technical Release requesting information and comments related to network composition

Comments deadline was extended, but concluded on October 17, 2023

MHPAEA Comment Activity

- The Departments of Labor, HHS, and Treasury have received over 9500 comment letters
- Many groups and organizations representing the interests of employers and plans sponsors have provided comments raising questions and concerns regarding a broad range of the proposed requirements. These include the American Benefits Council, the National Coordinating Committee of Multiemployer Plans, the ERISA Industry Committee, and the Parity Coalition.
- Comment letters are accessible for viewing by the public https://www.regulations.gov/docket/EBSA-2023-0010/comments?filter=

Key Takeaways

- In the year of ERISA's 50th Anniversary, plan sponsors can still expect to have to defend the exclusion from income for health benefits and ERISA preemption
- Regulatory and statutory efforts tending to put more requirements on plan sponsors to monitor actions of service providers

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Session Evaluation